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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

MARY PENNINGTON and MEGAN DOOLEY FISHER, individually and on behalf of all other similarly situated,

Plaintiffs,

v.

TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA PARENTERAL MEDICINES, INC., TEVA NEUROSCIENCE, INC., TEVA SALES & MARKETING, INC., and CEPHALON LLC,

Defendants.

No. 8:25-cv-01324

COMPLAINT

CLASS ACTION

DEMAND FOR JURY TRIAL

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Plaintiffs, individually and on behalf of all others similarly situated, bring this class action against Defendants and allege, based on personal knowledge as to themselves and upon information, belief, and the investigation of counsel as to the other allegations, as follows:

INTRODUCTION

1. This case seeks to hold Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., Teva Neuroscience, Inc., Cephalon LLC, and Teva Sales & Marketing, Inc. (collectively, "Defendants" or "Teva") accountable for participating in a scheme to improperly block access to the EpiPen (a life-saving drug/device combination for severe allergic reactions) in exchange for blocking access to Nuvigil (a wakefulness medicine). As a result, Teva enriched itself at the literal expense of American consumers who overpaid by hundreds of millions of dollars for these medications.

2. Teva worked in secret to sign deals with two other pharmaceutical manufacturers, Mylan and Pfizer, which foreclosed generic competition to both the EpiPen and Nuvigil for several years longer than legally allowed. In short, Mylan and Pfizer, on the one hand, and Teva, on the other, agreed to exchange market access for EpiPen and Nuvigil to protect their respective market shares and to delay entry of generic competition for their respective branded drugs. By abusing the patent litigation process and conspiring to block generic access, Teva, Mylan, and Pfizer forced purchasers to pay for branded products when prescriptions should have been filled with less costly generic

options. Teva is primarily a generic drug company that publicly claims to champion and promote generic drug access. Standing in stark contrast to these claims, Teva's secret efforts to block access to generic alternatives to Nuvigil and EpiPen were especially egregious.

3. As to the schemes to block generic drug access to Nuvigil and the EpiPen, there is little mystery as to what happened: Mylan and Pfizer have already settled a lawsuit filed against them concerning the generic delay scheme for a total of $609 million. *See In re EpiPen Marketing, Sales Practices, & Antitrust Litigation*, 17-md-2785 (D. Kan.) ("***In re EpiPen MDL***"). These nine-figure settlements, which occurred after years of discovery and nationwide class certification of claims for antitrust and RICO violations, confirm the plausibility of the allegations raised in this complaint against Teva.

4. But those settlements addressed only the EpiPen, and only Mylan and Pfizer's roles in the pay-for-delay scheme. This case—alongside a sister-case filed in Kansas that does not presently include California plaintiffs or pursue California claims: *Edgar et al v. Teva Pharmaceuticals Industries, Ltd. et al*, 2:22-cv-02501-DDC-TJJ (D. Kan.)—addresses the other side of the exchange, Nuvigil, and the other participant in the scheme, Teva. This case seeks to complete the puzzle and to hold Teva accountable for its role in delaying generic options for Nuvigil.

PARTIES

5. Plaintiff Mary Pennington is a citizen of California who, on information and belief, paid for part of the purchase price of Nuvigil during the Nuvigil Class Period.

6. Plaintiff Megan Dooley Fisher is a citizen of California and paid for part of the purchase price of Nuvigil during the Nuvigil Class Period.

7. Intentionally left blank.

8. Intentionally left blank.

9. Intentionally left blank.

10. Intentionally left blank.

11. Defendant Teva Pharmaceuticals Industries, Ltd. ("Teva Ltd.") is a worldwide pharmaceutical company engaged in the development, manufacturing, marketing, and sale of pharmaceutical products. Teva Ltd. is an Israeli company, having its principal place of business at 124 Dvora HaNevi'a Street, Tel Aviv, Israel 6944020.

12. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva USA is a wholly owned subsidiary of Teva Ltd., acts as an agent of Teva Ltd., and develops, manufactures, processes, and markets pharmaceutical drug products for sale and use throughout the United States, including within this District.

13. Defendant Teva Parenteral Medicines, Inc. ("Teva Parenteral") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and during the relevant time period and when the conduct at issue in this action occurred, Teva Parenteral was located at 19 Hughes, Irvine, California 92618. Upon information and belief, Teva Parenteral is a wholly owned subsidiary of Teva USA,

acts as an agent of Teva Ltd. and Teva USA, and develops and markets generic injectable drug products for sale and use throughout the United States, including within this District.

14. Defendant Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and during the relevant time period and when the conduct at issue in this action occurred Teva Neuroscience was located at 11100 Nall Avenue, Overland Park, Kansas 66211. Upon information and belief, Teva Neuroscience is a wholly owned subsidiary of Teva Ltd., acts as an agent of Teva Ltd. and, in turn, Teva USA, and develops, manufactures, processes, and markets neurological drug products for sale and use throughout the United States, including within this District.

15. Defendant Cephalon, LLC. ("Cephalon") is a Delaware corporation with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. Cephalon is a wholly owned subsidiary of Teva Ltd., acts as an agent of Teva Ltd. and, in turn, Teva USA, and develops, manufactures, processes, and markets neurological drug products for sale and use throughout the United States, including within this District.

16. Defendant Teva Sales & Marketing, Inc. ("Teva Sales") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054 and when the conduct at issue in this action occurred Teva Sales was located at 11100 Nall Avenue, Overland Park, Kansas 66211. Upon information and belief, Teva Sales acts as an agent of Teva Ltd. and, in turn, Teva USA and markets and

sells neurological drug products for sale and use throughout the United States, including within this District.

17. Intentionally left blank.

18. Teva Ltd., Teva USA, Teva Parenteral, Teva Neuroscience, Cephalon, and/or Teva Sales were individually and collectively involved in the alleged schemes.

19. Teva Ltd. controls, directs, and supervises the sales and marketing activities of Teva USA and Teva Sales, as well as their employees. Teva USA in turn controls, directs, and supervises the sales and marketing activities of Teva Parenteral, Teva Neuroscience, and Cephalon, as well as their employees.

20. Teva Ltd. repeatedly describes itself as a single, "global" entity. Teva Ltd.'s Code of Conduct addresses its "global workforce" and declares that it is "[t]housands of people, across many countries, speaking a multitude of languages, with one mission," which is "to be a global leader in generics and biopharmaceuticals."[1] Teva Ltd.'s Statement of Corporate Governance Principles emphasizes the "complexity of Teva's businesses and its extensive global activity."[2] Teva Ltd.'s Code of Conduct further states that "[w]e understand that in order to achieve our common goals we need to engage our

[1] Teva Ltd., *Teva's Code of Conduct*, (Dec. 9, 2020), https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf ("Teva's Code of Conduct").

[2] Teva Ltd., *Statement of Corporate Governance Principles*, at 1 (last updated Nov. 4, 2020) https://www.tevapharm.com/globalassets/tevapharm-vision-files/statement-of-corporate-governance-principles---november-2020.pdf ("Statement of Corporate governance Principles").

employees around the world, across different divisions and in different functional areas."[3] Teva Ltd. boasts that "[o]ur work impacts economies and healthcare systems around the world."[4]

21. According to facts unsealed by the district court's order in *City and Cnty. of San Francisco v. Purdue Pharma L.P.* ("SF Order"), 491 F. Supp. 3d 610, 636 (N.D. Cal. 2020), "Teva Ltd. depicts itself as 'One global brand, One story, One Teva,' . . . and [Teva Ltd.'s] indirect subsidiaries report directly to Teva Ltd." *Id.* "According to a 2018 'Segment Memorandum,' Teva Ltd.'s CEO is 'ultimately responsible' for allocating all of Teva's resources." *Id.* "Around the same time, Teva Ltd. implemented 'a new organizational structure' to help integrate Teva 'into one commercial organization,' thereby blurring the layers of separation between Teva Ltd. and its subsidiaries." *Id.*

22. The SF Order also found that "[t]he head of Teva Ltd.'s Global Research and Development division controls Teva's product formulation, design, and commercial execution." *Id.* Indeed, Teva Ltd. claims that it has a "fully integrated R&D function" that has accomplished 100 "pending first-to-file ANDAs in the U.S." and 270 "product registrations pending FDA approval."[5] The SF Order also found that "Teva Ltd. implemented guidelines that enabled it to nominate, select, and approve the Executive

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[3] Teva's Code of Conduct at 22, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

[4] *Economic Impact Report*, Teva Ltd., https://www.tevapharm.com/our-impact/economic-impact-report.

[5] Teva Ltd., *Facts and Figures*, (May 2020) https://www.tevapharm.com/globalassets/scs-files---global/teva-infographic-files/teva_infographic_english_may2020.pdf

Committee and Sub-committee members for itself and its U.S. subsidiaries, resulting in substantial control over the subsidiaries' marketing, administration, manufacturing, research and development, purchase of supplies, finance, and 'other significant supporting operations conducted in "shared and commingled assets."'" *Id.* at 636-37.

23. Teva Ltd. and Teva USA also share employees and corporate officers, with Teva Ltd. controlling the activities of Teva USA. According to facts unsealed by the district court's order in *In re Nat'l Prescription Opiate Litig.*, 1:17-MD-2804, 2019 WL 3553892, at *4 (N.D. Ohio Aug. 5, 2019), the state alleged that "Teva Ltd. controls the operations of its subsidiaries through an integrated management team via Global Divisions" and "Debra Barrett, as [a] Teva USA employee, coordinated and directed advocacy, lobbying, and policy development across the entire Teva group of companies." *Id.* "Any proposed corporate contribution or political activity" conducted by Teva Ltd. or its subsidiaries is required to "be reviewed and approved by Teva [Ltd.]'s Global Government Affairs and Public Policy Department."[6] The Compliance Committee of Teva Ltd.'s Board of Directors has the responsibility to "review and oversee the Company's global public policy positions and government affairs activities."[7] "Teva's Tax function is

[6] Teva's Code of Conduct at 17, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

[7] Teva Ltd., *Compliance Committee Charter*, at 2 (Dec. 3, 2020), https://www.tevapharm.com/globalassets/tevapharm-vision-files/compliance-committee-charter-december3-2020-new-format.pdf.

organized on a global basis to ensure consistent tax policies, strategies and processes across regions and locations for all tax aspects at all levels."[8]

24. Teva Ltd.'s global "[m]arketing and promotional practices are under the responsibility of [Teva Ltd.'s] Executive Vice President for Global Marketing & Portfolio."[9] Moreover, "Teva [Ltd.]'s global internal audit department periodically audits marketing and promotional material compliance."[10] And with respect to marketing and promotional practices, Teva Ltd. describes how it "maintains a global and comprehensive compliance and ethics program that meets or exceeds all of the elements proposed by the U.S. Department of Justice, Office of the Inspector General," including "a systematic annual risk assessment supported by corrective actions as required across different Teva divisions and in different markets."[11]

25. Teva also adopted an enterprise-wide customer relations management ("CRM") system in 2014.[12] According to a press release announcing the change,

[8] Teva Ltd., *Teva's Group Tax Policy*, at 4, https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva-global-tax-policy-26072020.pdf.

[9] Teva Ltd., *Teva's Position on Marketing and Promotional Practices*, at 3, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-marketing-position-_2020.pdf.

[10] *Id.*

[11] *Id.*

[12] *Teva Harmonizes All Commercial Teams Worldwide with Veeva Systems' Cloud-based CRM Solution*, Businesswire (May 28, 2014, 7:03 AM), https://www.businesswire.com/news/home/20140528005686/en/Teva-Harmonizes-All-Commercial-Teams-Worldwide-with-Veeva-Systems'-Cloud-based-CRM-Solution.

> In an enterprise-wide drive to harmonize its commercial operations, Teva Pharmaceuticals is standardizing on Veeva Systems' multichannel CRM system. Teva is replacing its legacy systems across 45 markets worldwide with Veeva's cloud-based solution to streamline operations and enable global collaboration across both generic and branded drug commercial teams. Veeva CRM, already deployed across U.S. field teams, is now being rolled out in Europe with plans to phase in other Teva regions over the next several months.[13]

In discussing the change, Teva Ltd.'s Chief Information Officer, Guy Hadari, stated that "Veeva CRM provides us the foundation for long-term success by allowing us to capture valuable customer insights about channel preferences and content needs globally."[14] He further explained that Veeva "increases efficiency by connecting commercial teams and regions in the cloud that had been highly fragmented."[15]

26. Teva Ltd. utilizes global policies that govern its operations throughout the world, including within the United States. Teva Ltd. has a global "Policy on the Prevention of Corruption," which is overseen by a Global Chief Compliance & Ethics Officer.[16] Teva

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[13] *Id.*

[14] Veeva Systems, *Teva Pharmaceuticals Unifies Global Commercial Strategy with Veeva CRM*, at 2, https://www.veeva.com/wp-content/uploads/2016/03/Teva-UK-Veeva-CRM-Case-Study-NA.pdf.

[15] *Id.*

[16] Teva Ltd., *Prevention of Corruption*, https://www.tevapharm.com/globalassets/tevapharm-vision-files/prevention-of-corruption---v2---04.15.18---english-ethics.pdf.

Ltd. also has a "Global Customs and Trade Controls Policy" and a "Global Data Privacy Policy."[17] Teva Ltd. explains the importance of its global trade controls by noting that "Teva does business all over the world, and the laws of one country or jurisdiction may apply to transactions or activities that occur elsewhere."[18] Additionally, Teva Ltd.'s "Board has adopted a global 'whistleblower' policy, which provides employees and others with an anonymous means of communicating with [Teva Ltd.'s] Audit Committee."[19]

27. Teva Ltd. has represented in court filings that it is "substantially identical" to one of its wholly owned U.S. subsidiaries,[20] and that it participates in the sale and/or management of facilities in the United States[21] and business lines in the United States.[22]

28. Teva Ltd.'s contacts with the United States include conduct relevant to this lawsuit and its control over its U.S. subsidiaries includes conduct relevant to the claims here. On April 30, 2012, Teva Ltd. announced that "that it has settled patent infringement

[17] Teva's Code of Conduct at 18, 28, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

[18] *Id.* at 18.

[19] Teva Ltd., Statement of Corporate Governance Principles at 4, https://www.tevapharm.com/globalassets/tevapharm-vision-files/statement-of-corporate-governance-principles---november-2020.pdf.

[20] *Zydus Worldwide DMCC v. Teva Pharmaceuticals Industries Inc.*, Docket No. 654824/2019 ("*Zydus*"), NYSCEF No. 15 at 14-16.

[21] *Teva Pharmaceutical Industries Ltd. vs. Dr. Reddy's Laboratories*, Index No. 656499/2021, NY Sup. Ct., NY County, Comm. Division, NYSCEF Nos. 29 (at ¶¶ 3, 4, 38, 39, 44, 46), 33 (at ¶ 63), 38.

[22] *Zydus Worldwide DMCC v. Teva Pharmaceuticals Industries Inc.*, Docket No. 654824/2019 ("*Zydus*"), NYSCEF No. 1 at ¶¶ 10, 15.

litigation regarding U.S. Patent Number 7,132,570 (the "'570 patent") with respect to Mylan Inc.'s ANDA for Teva's wakefulness product NUVIGIL® (armodafinil) tablets."

JURISDICTION AND VENUE

29. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 (exclusive of interest and costs), the number of members of each of the putative Classes exceeds 100, and at least one member of the putative Classes is a citizen of a state different from that of one of the defendants. This Court also has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1337.

30. This Court has supplemental jurisdiction over Plaintiffs' pendent state-law claims pursuant to 28 U.S.C. § 1367.

31. This Court has personal jurisdiction over Defendants because they conduct business in this State, have purposefully directed their actions toward this State, and have sufficient minimum contacts with this State. Defendants intentionally avail themselves of the markets in this State through the promotion, marketing, and sale of the products at issue in this lawsuit. Moreover, Plaintiffs' claims arise out of, or relate to, Defendants' contacts with this District. Defendants are co-conspirators and each has minimum contacts with this District and has purposefully availed itself of the privilege of conducting business in this State.

32. Alternatively, this Court has personal jurisdiction over Teva Ltd. because Teva Ltd. is an alter ego of its United States subsidiaries, Defendants Teva USA, Teva

Neuroscience, Teva Parenteral, Cephalon, and Teva Sales, over which this Court has personal jurisdiction for the reasons stated in the preceding paragraph.

33. This Court's exercise of personal jurisdiction over Teva Ltd. satisfies due process because Teva Ltd. conducts business in the United States, has purposefully directed its actions toward the United States, and has sufficient minimum contacts with the United States.

a. Teva Ltd. intentionally avails itself of U.S. markets. Teva Ltd. describes itself as "the leading generic pharmaceutical company in the United States."[23] It acknowledges that it is subject to "extensive" regulation by the United States, including inspection of its facilities by FDA, among other significant regulatory burdens.[24]

b. Teva Ltd. further intentionally and repeatedly avails itself of the federal court system as a plaintiff in patent-related litigation, including the very products issued in this lawsuit.

c. Teva Ltd. directs activities, submissions, and dealings with the U.S. Food and Drug Administration and Federal Trade Commission.

d. Plaintiffs' claims arise out of, or relate to, Teva Ltd.'s contacts with the United States.

[23] Teva Ltd., Annual Report (Form 10-K) for the fiscal year ended December 31, 2019 at 3; *see also id.* at 5 ("We are the [Generic Medicines] market leader in the United States…") ("Teva Ltd. 2019 10-K").

[24] *Id.* at 19-20.

34. Venue is proper in this forum pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to these claims occurred in this District, including Nuvigil sales made by Defendants; each Defendant is subject to personal jurisdiction in this District; and Defendants have registered to do business and/or transact business in this District.

BACKGROUND AND FACTUAL ALLEGATIONS

A. Overview of the Pay-For-Delay (Trade-For-Delay) Scheme

35. The pay-for-delay scheme at the heart of this action involved an illegal allocation of markets for two branded drugs: EpiPen and Nuvigil. Mylan and Pfizer controlled the branded EpiPen, while Teva, through its subsidiary Cephalon, controlled branded Nuvigil.

36. In November 2008, Teva filed an application with the FDA seeking to bring to market a generic version of the EpiPen—a very profitable brand-name drug-device intended for the emergency treatment of persons suffering from life-threatening allergic reactions.

37. Upon seeing Teva's application to offer generic competition, Pfizer (which held the patents to the EpiPen) promptly sued Teva for patent infringement.

38. Just a few months later, in July 2009, Mylan filed an application with the FDA seeking to bring to market a generic version of Nuvigil—a very profitable brand-name wakefulness drug often used to treat narcolepsy, shift-work disorders, and certain other sleep-related disorders. Cephalon promptly sued Mylan for patent infringement.

39. Rather than fully litigate the two separate cases (and thus face the risk of the patents on one or both of their lucrative products failing in court), the three parties (Mylan, Pfizer, and Teva) secretly agreed to a quid pro quo in which each side agreed, via collusive settlements in the respective patent litigations, to allow the other to maintain its respective brand-drug monopoly much longer than either could reasonably expect were they to fully litigate their cases against each other over each product.

40. Neither settlement standing alone was economically rational for the generic entrant, and, taken together, the settlements produced greater profits than the parties could have achieved by not linking the settlements. These greater profits came at the expense of American drug purchasers, who were denied the ability to buy generic drugs and instead were forced to pay far higher prices for the same medications.

41. As two of the largest generic drug companies, Mylan and Teva knew exactly what they were doing and willfully sought to restrain generic access to American drug purchasers—despite publicly trumpeting the importance, safety, equivalence, and vital role that generic drugs play for American consumers and payers.

42. The scheme to delay competition was two-fold: Mylan and Pfizer agreed with Teva to "trade" much-delayed entry dates for their respective generic competitor to the others' branded drugs. Mylan and Pfizer agreed to delay launching a generic drug that would undercut Nuvigil, and Teva agreed to delay launching a generic drug/device that would undercut the EpiPen. As a result, the three entities illegally wiped out all generic competition for years—ensuring they each generate in revenues far more on their

respective monopoly drug than they ever would from allowing the market to operate freely with a generic competitor into the other's markets.

43. The benefits were simple and substantial. It was well known and understood at the time that generic competition to the EpiPen and Nuvigil would hurt the profits that Teva and Mylan/Pfizer could earn from their respective branded drugs. Teva and Mylan are primarily generics companies, and profit margins on generic drugs are thin. The EpiPen and Nuvigil, being branded products, were their "cash cows" that uniquely allowed them to obtain higher margins (and thus higher profits). Both Teva and Mylan sought to artificially extend their branded drug revenue streams from their high-margin branded products.

44. By suppressing a generic competitor from launching, Teva illegally earned hundreds of millions of dollars in overcharges that it never should have received. But-for the secret agreement between Mylan/Pfizer and Teva, multiple generic competitors to Nuvigil would have launched, and the generics would have taken over 90% of the market from the branded drug.

45. Generic drugs, on average, cost 80-85% less than their brand-name counterparts. It is widely known among pharmaceutical companies—and the Wall Street analysts and traders who determine their stock prices—that "generic drugs quickly take

sales from brand drugs. Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months."[25]

B. The Scheme to Block Generic Competition to the EpiPen

46. Anaphylaxis is a serious allergic reaction that can be life-threatening if not promptly and properly treated.

47. Epinephrine is the recognized first-line treatment for anaphylaxis.[26]

48. An epinephrine auto-injector ("EAI") is a device used to self-deliver a controlled dose of epinephrine.[27]

49. EAIs have been available in the U.S. since the 1980s, when the EpiPen EAI first was approved by the FDA and marketed to consumers.[28]

1. Pfizer owns the EpiPen intellectual property and Mylan exclusively marketed and distributed EpiPens.

50. In 2007, Mylan Pharmaceuticals, Inc. acquired Dey Pharma L.P. ("Dey"), which later was renamed Mylan Specialty, L.P.[29]

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[25] Michael A. Carrier, et al., *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 312 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr.

[26] *In re EpiPen MDL*, 545 F. Supp. 3d 922, 931 (D. Kan. 2021) (granting summary judgment on RICO claim but denying summary judgment on antitrust claims), *reconsideration denied*, No. 17-MD-2785-DDC-TJJ, 2021 WL 4948269 (D. Kan. Oct. 25, 2021).

[27] *Id.* at 932.

[28] *Id.*

[29] *Id.*; Mylan Inc., *Mylan to Change Name of Specialty Subsidiary From Dey Pharma to Mylan Specialty* (Feb. 15, 2012) https://investor.mylan.com/news-releases/news-release-details/mylan-change-name-specialty-subsidiary-dey-pharma-mylan.

51. At that time, Dey had the exclusive right and license to market, distribute, and sell the EpiPen Auto-Injector in the United States under a Supply Agreement with Meridian Medical Technologies, Inc. ("Meridian"),[30] which manufactures the EpiPen products.[31] From 2007 until 2020, when Mylan was merged into a new entity (Viatris), Mylan Specialty marketed and sold EpiPen devices, which Meridian supplied under the Supply Agreement.[32]

52. The Supply Agreement established a "Joint Commercial Committee" ("JCC") designed to streamline the "distribution of EpiPen products."[33]

53. The Supply Agreement required Meridian to "prosecute and maintain any patents or patent applications" for EpiPen products.[34] Relatedly, the Supply Agreement required the parties to notify each other of potential infringement and "jointly determine in good faith the appropriate course of action[.]"[35]

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[30] *In re EpiPen MDL*, 545 F. Supp. 3d 922, 932 (D. Kan. 2021) (granting summary judgment on RICO claim but denying summary judgment on antitrust claims), *reconsideration denied*, No. 17-MD-2785-DDC-TJJ, 2021 WL 4948269 (D. Kan. Oct. 25, 2021). Meridian is a subsidiary of Pfizer Inc. Pfizer acquired King Pharmaceuticals LLC ("King") and Meridian in 2011. And now, Meridian and King are indirect wholly owned subsidiaries of Pfizer, Inc. *Id.* at n.6.

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.* at 953.

54. Meridian held the "New Drug Application" ("NDA") for EpiPen and was thus responsible for filing advertising and promotional materials with the FDA until July 2013, when Pfizer transferred the NDA to Mylan.[36]

55. Between 2009 and 2016, Mylan increased the EpiPen's Wholesale Acquisition Costs ("WAC"), also known as the list price, multiple times.[37] The WAC is a list price that manufacturers charge wholesalers.[38] The WAC is not the price that consumers or health plans pay for pharmaceutical products.[39]

56. As a result of these price increases, and Mylan's decision to force U.S. consumers to buy EpiPens in packages of two, the price of the EpiPen rose from the $100s to $600s, far surpassing the rate of inflation.

2. Teva develops a generic competitor to the EpiPen.

57. The EpiPen was highly profitable for Mylan. Teva had been working since 2007—if not earlier—to launch a generic EAI that would undercut Mylan on price and capture the huge market of EpiPen sales.

58. Generic drug approval was required. EAIs, like any other prescription drug or drug-device combination product, may not be sold in the United States until gaining FDA approval.[40]

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[36] *Id.* at 932.
[37] *Id.* at 935.
[38] *Id.*
[39] *Id.*
[40] *Id.* at 946.

59. To secure FDA approval, an Abbreviated New Drug Application ("ANDA") must be submitted. Approval of the ANDA is required before a new generic product may be sold or marketed in the United States.[41]

60. In the context of an ANDA, the FDA sometimes uses the phrases "Reference Listed Drug" ("RLD") and "innovator drug" to refer to the branded product to which the FDA will compare the proposed generic.[42]

61. Since 1984, the Hatch-Waxman Amendments (the "Hatch-Waxman Act") have provided a framework for the FDA to evaluate ANDA applications while also allowing generic manufacturers to challenge patents associated with RLDs.[43]

62. Under the Hatch-Waxman Act, all ANDA applicants, and certain NDA applicants, must make certifications for patents associated with their RLD counterparts, including a "Paragraph IV certification," which is a certification by the applicant that, "in the opinion of the applicant," the relevant patent is "invalid or will not be infringed by" the new proposed generic product.[44]

63. Any applicant filing a Paragraph IV certification must notify the holder of the relevant patent and the holder of the approved drug application who claims that patent.[45]

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[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.* at 947.
[45] *Id.*

64. Once a patent holder receives a Paragraph IV certification, it may file an infringement suit within 45 days, triggering an automatic 30-month stay of FDA approval of the ANDA.[46]

65. In 2007, Teva filed ANDA 90-0589 to develop a generic EAI.[47] Upon review, the FDA deemed Teva's application "acceptable for filing" on November 21, 2008.[48]

66. With its ANDA, Teva's goal was to develop and secure approval for a generic product that the FDA would consider "A-rated" to the EpiPen EAI.[49]

67. When Teva submitted its ANDA, Pfizer's subsidiary Meridian held a patent on the auto-injector component of the branded EpiPen product.[50]

68. To secure approval of its ANDA, Teva had to demonstrate that its device was "equivalent to" the EpiPen.[51]

69. At the same time, however, Teva could not just copy the EpiPen without infringing on patents held by Pfizer's subsidiaries—assuming the EpiPen patents were valid at all.[52]

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[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.* An A-rating (sometimes referred to as "AB" or "AP" in the context of injectable products) signifies that two products are "therapeutically equivalent" and can be substituted for one another at the pharmacy counter. *Id.* at n.19.
[50] *Id.* at 948.
[51] *Id.*
[52] *Id.*

70. To avoid infringing these patents, Teva's proposed generic product for which it sought FDA approval included a different auto-injector than EpiPen.[53]

3. Pfizer and Mylan sue Teva over its generic EpiPen competitor.

71. In July 2009, consistent with the Hatch-Waxman Act, Teva notified King and Meridian that it had filed ANDA 90-0589 to market a generic version of EpiPen Auto-Injector and had submitted a Paragraph IV certification.[54]

72. Then, on August 28, 2009, King and Meridian sued Teva in the District of Delaware to enforce U.S. Patent No. 7,449,012B2 (the "'012 Patent").[55]

73. Mylan and Pfizer entered a Common Interest Agreement in connection with the EpiPen patent litigation against Teva.[56]

74. On November 1, 2010, Teva submitted a Paragraph IV certification concerning an additional Pfizer EpiPen patent: U.S. Patent No. 7,794,432B2 (the "'432 Patent").[57]

75. On November 11, 2010, King and Meridian amended their Complaint in the Delaware suit against Teva to enforce the second patent.[58]

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[53] *Id.*

[54] *Id; see also King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Aug. 28, 2009).

[55] *In re EpiPen MDL*, 545 F. Supp. 3d 922, 948 (D. Kan. 2021) (granting summary judgment on RICO claim but denying summary judgment on antitrust claims), *reconsideration denied*, No. 17-MD-2785-DDC-TJJ, 2021 WL 4948269 (D. Kan. Oct. 25, 2021).

[56] *Id.*

[57] *Id.* at 950.

[58] *Id.*

76. Both the ’012 and ’432 Patents are listed in the FDA Orange Book and expire in September 2025.[59] Both patents were weak, and all parties would have known that Pfizer’s suit was very unlikely to succeed. In fact, Pfizer voluntarily dismissed its claims based on the ‘432 patent, indicating that it and Mylan knew the ’432 patent was not a viable basis for a patent infringement claim.

77. In March 2011, Teva and Pfizer discussed in an email titled “Fre 408: couple of things” setting up a phone call to discuss the Teva/EpiPen patent infringement litigation.[60]

78. On February 16, 2012, the EpiPen bench trial began.[61]

4. Teva, Pfizer, and Mylan agree to a trade-for-delay scheme to settle the EpiPen generic litigation.

79. On April 26, 2012, Pfizer and Teva executed a binding term sheet that granted Teva a license to launch its EAI on or after June 22, 2015, subject to FDA approval.[62]

80. Since both Mylan and Teva had previously been fined by the federal government for a pay for delay scheme involving another drug called Provigil, Pfizer (or Mylan) and Teva sought to employ a trade for delay scheme that would be harder for the federal government to detect.

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[59] *Id.*
[60] *Id.* at 950-51.
[61] *Id.* at 951. *See* Day 1 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. July 25, 2012).
[62] *Id.* at 952.

81. On July 20, 2012, Pfizer and Teva executed the final Settlement and License Agreement to resolve the EpiPen litigation.[63]

82. Mylan was not a direct signatory to the binding term sheet or the Settlement and License Agreement, but on that same date, and as a requirement of Teva's agreement, Mylan executed a Covenant Not to Sue Teva with respect to any EpiPen patents in the ownership or control of Mylan.[64] The Covenant Not to Sue was attached to and made a part of the settlement agreement.[65]

83. Mylan witnesses testified that Mylan received updates from Pfizer about the Teva litigation, including during trial and settlement negotiations.[66]

84. Then-President and CEO of Teva-Americas William Marth had extensive and repeated direct communications by telephone with Mylan CEO Heather Bresch about both the Teva/EpiPen settlement and the Nuvigil settlement.[67]

85. In those discussions, Mr. Marth "talked to Heather . . . about settlement" of the EpiPen litigation and stated to his confederates that "[s]he (Heather) wants to give us a 2018 entry date but would likely agree to 2017" and noted that "[j]ointly but not directly connected is the Nuvigil litigation" where Mr. Marth "offered a 2018 entry date."[68]

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[63] *Id.* at 953.
[64] *Id.*
[65] *Id.*
[66] *Id* at 953.
[67] *Id.*
[68] *Id.*

86. Further communication also revealed that "Bill [Marth] got a call from Heather at Mylan" asking what "exactly did we propose re epi and nuvigil?" and responding in another email with "2014 for epi and 2018 for nuvigil. No months specified."[69]

87. Finally, those Marth/Bresch discussions culminated in sending the Nuvigil term sheet by email and discussing changes that were "agreed to between Heather and Mr. Marth."[70]

88. Other Mylan and Teva employees also discussed the EpiPen and Nuvigil settlements in the same communications, using the interstate wires to do so. For example, Teva called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018"[71] and noted that "the signed Nuvigil deal was" complete and "language w Pfizer on Epipen is done."[72]

89. Further, Mylan employees emailed with the subject line "Epipen—Teva/Potential Settlement" and attached a "Nuvigil Settlement DRAFT."[73]

90. Likewise, several Teva/Mylan/Pfizer emails and documents reveal that Mylan's lawyers spoke with Teva and Pfizer about the settlement using telephones or by

[69] *Id.* at 960-61.
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*

email—all using the interstate wires to orchestrate and execute their suppression of free market generic competition.[74]

91. On April 26, 2012, Mylan and Pfizer issued a joint press release announcing that "Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Teva that will resolve pending patent litigation related to [the Teva/EpiPen litigation]."[75] The press release left out that the EpiPen settlement was part of a quid pro quo for Mylan's agreement to simultaneously enter into a settlement agreement resolving the Nuvigil patent litigation in Teva's favor.

92. The settlement agreement gave Teva a license to all issued patents and a covenant not to sue based on any current or future patents covering EpiPen devices (including the '035 Patent not at issue in the litigation, and any future patents like the '827 Patent).[76] But Teva agreed that its new license to market a generic EAI would not be effective until mid-2015, three years later.[77]

93. The joint press release doesn't say that Mylan was or was not a party to the suit or settlement and others within Mylan reviewed and provided comments on the press release.[78]

94. Also, several months after the settlement, in a July 2012 earnings call, Heather Bresch commented that "the runway was absolutely clear . . . through 2015,

[74] *Id.* at 953.
[75] *Id.* at 953-54.
[76] *Id.* at 954.
[77] *Id.* at 952.
[78] *Id.* at 954.

through *our settlement* with Teva"[79]—again confirming that Mylan was involved (not merely Pfizer). In that call, Ms. Bresch left out that the EpiPen settlement was part of a quid pro quo for Mylan's agreement to simultaneously enter into a settlement agreement resolving the Nuvigil patent litigation in Teva's favor.

95. The EpiPen patent settlement agreement did not contain any monetary payment.[80] Instead, the parties decided to trade protection for their respective branded drugs' market share by blocking generic competition through agreed-upon entry dates, rather than monetary payments.

5. Teva delays its generic EpiPen pursuant to the trade-for-delay scheme.

96. Teva is a large, sophisticated pharmaceutical company "skilled in the art" of drug development, especially generic drug development and launch.[81]

97. Internal Teva documents from late 2011 and early 2012 projected that Teva would launch its generic EAI by 2014.[82]

98. On July 31, 2013, Teva sent a letter to the FDA responding to a deficiency letter dated March 29, 2010—more than three years earlier.[83]

99. On August 29, 2013, Teva submitted its first human factors study to the FDA—responding to the FDA's deficiency letter of May 17, 2011.[84]

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[79] *Id.* (emphasis in original).
[80] *Id.*
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*

100. In 2014, an internal Teva document estimated the net present value of the EpiPen generic at $193 million—$70 million more than any other product Teva was working to develop.[85]

101. As it worked to secure FDA approval, Teva implemented a "Tiger Team" to work on its generic EAI.[86]

102. One Teva communication defined a "Tiger Team" as "a group of experts assembled to solve a crisis or to have a reliable/predictable performance on important projects and/or tasks with high priorities."[87]

103. In May 2014, Rosario Lobrutto asked for "more resources (and the right resources/best experts) to address current issues[.]"[88]

104. She asked for 8.5 additional persons "to backfill the resource gaps[.]"[89]

105. Teva agreed to "reallocate [its] existing resources from agreed upon other projects (with portfolio) to Epi[.]"[90]

106. On August 16, 2018, the FDA approved Teva's ANDA.[91]

107. Each EAI's expiration date is generally about 12 months from the date of purchase. As a result, consumers typically replace their EAI's only about once a year, assuming they are not lost or used before then. Thus, even though Teva's generic EpiPen

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[85] *Id.* at 955.
[86] *Id.*
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] *Id.* at 957.

finally began its rollout in late 2018, it took more than a year for Teva's generic EpiPen to capture its full ultimate market share and achieve its full effect on the lowering of EAI prices.

108. Dr. Carl Peck, a former FDA official, has calculated that it took Teva "9 years and 9 months" to secure FDA approval.[92]

109. He measures that time starting on November 21, 2008—when the FDA accepted Teva's ANDA for filing—and ending on August 16, 2018—the date the FDA approved Teva's generic.[93]

110. Dr. Peck compared the time it took Teva to secure FDA approval to those of other EAI manufacturers, and he explained that "none have required the lengthy time for review and approval exhibited by the Teva generic EAI."[94]

111. He asserts that "the other EAIs all were subject to the more stringent NDA standards (as opposed to ANDA standards)" yet "most were approved in 2–3 years, while the longest review and approval time was 6.5 years from initial filing."[95]

112. Also, Dr. Peck reviewed the approval time for other auto-injector products.[96]

[92] *Id.* at 958.
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*

113. He notes that with other auto-injector products that "[a]gain, none have required the lengthy time for review and approval exhibited by the Teva generic epinephrine autoinjector."[97]

114. Instead, the approval time for other auto-injector products has ranged from six months to 69 months.[98]

115. Dr. Peck asserts that this data shows "autoinjectors are common, their technology is well-developed, and that all of the autoinjectors on the market today were reviewed and approved in less than half the time of the Teva EAI."[99]

116. Also, "at least six of the EAIs" that Dr. Peck lists "required an HFS[,]" which, he asserts, "shows that Teva had the same opportunity as other EAI manufacturers to develop and prosecute ANDA and NDA injectable products within a reasonable time period."[100]

117. Dr. Peck reviewed other Teva injectable products and opines that "on average, they were approved in under 30 months."[101]

118. Dr. Peck notes that "the longest submission to approval time" for the other Teva injectable products "was 48 months or about one half the time" that it took Teva to secure approval of its generic EAI.[102]

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*

119. Dr. Peck concluded that "the FDA review and guidance did not delay the approval of Teva's application."[103]

120. "On the contrary," he asserts, "the evidence confirms that the FDA treated this as a priority application and was responsive well within the metrics for review time of the application."[104]

121. "Teva 'dropped the ball' in the 2011–2014 time frame by not pursuing the application aggressively or responding to the FDA[.]"[105]

122. Based on his review of Teva's communications with the FDA, he concludes that "it is reasonable to expect that the FDA would have completed its review and approval of Teva's EAI application by 2014 . . . if not earlier—had Teva been responsive to the FDA's requests in prosecuting its application."[106]

123. But for Teva's EpiPen-for-Nuvigil agreement with Mylan, it would have exercised greater diligence in seeking approval for its generic EpiPen and would have entered the marketplace well before the EpiPen settlement's allowed entry date in June 2015. As a result of the conspirators' scheme to delay the entry of Teva's generic version of the EpiPen, patients and payors in all 50 states were prevented from obtaining a less expensive, bioequivalent version of the EpiPen and instead, in every state, patients and

[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.*

payors paid millions of dollars more in supracompetitive and artificially-high prices for brand EpiPen.

6. Mylan's EpiPen revenue craters after Teva releases its generic competitor.

124. The EpiPen became a blockbuster drug with revenues of over $1 billion a year throughout the period of the scheme with Teva. Mylan could raise the price of the EpiPen because it had no concerns of generic competition as a result of its scheme with Teva. As a result of delaying patients' access to a generic EAI, Mylan reaped hundreds of millions of dollars in extra revenues.

C. The Scheme to Block Generic Competition to Nuvigil

125. In 2009, the pharmaceutical company Cephalon, Inc. launched a branded drug called Nuvigil.[107]

126. Nuvigil is a "prescription drug" used to "improve wakefulness in patients with excessive sleepiness."[108]

[107] BioSpace, *Cephalon, Inc. Announces the Availability of NUVIGIL for the Treatment of Excessive Sleepiness Associated with Treated Obstructive Sleep Apnea, Shift Work Disorder and Narcolepsy* (Jun. 1, 2009), https://www.biospace.com/article/releases/cephalon-inc-announces-the-availability-of-nuvigil-for-the-treatment-of-excessive-sleepiness-associated-with-treated-obstructive-sleep-apnea-shift-/.

[108] *In re EpiPen*, 545 F. Supp. 3d at 959.

1. Teva owns Nuvigil.

127. In October 2011, Teva acquired Cephalon, Inc. as a wholly owned subsidiary.[109]

128. When Teva acquired Cephalon, it also acquired Cephalon's drug, Nuvigil.[110] Following the acquisition, Teva and Cephalon manufactured, distributed, and sold Nuvigil, which immediately became one of Teva's most profitable products.

129. In the fourth quarter of 2011, Teva realized $86 million of net revenue from Nuvigil sales.[111]

130. In 2012, Teva realized $347 million of net revenue from Nuvigil sales.[112]

131. In 2013, Teva realized $320 million of net revenue from Nuvigil sales.[113]

132. In 2014, Teva realized $388 million of net revenue from Nuvigil sales.[114]

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[109] *Id.;* Teva Pharm. Indus., *Teva Completes Acquisition of Cephalon* (Oct. 14, 2011), https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2011/Teva-Completes-Acquisition-of-Cephalon/default.aspx.

[110] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 17, 2012) at 27, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/b9c63d90-fe61-4d2b-ad6e-8944cf064356.pdf.

[111] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 17, 2012) at 61, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/b9c63d90-fe61-4d2b-ad6e-8944cf064356.pdf.

[112] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 10, 2014) at 64, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/089262e5-886d-4090-acdd-d5b4c6622374.pdf.

[113] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 10, 2014) at 64, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/089262e5-886d-4090-acdd-d5b4c6622374.pdf.

[114] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 11, 2016) at 64, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/64b7ff41-922a-4b39-afa6-27d50cd5adc9.pdf.

133. In 2015, Teva realized $373 million of net revenue from Nuvigil sales.[115]

2. Teva sues Mylan for patent infringement over its generic Nuvigil competitor.

134. On December 11, 2009, Cephalon (not yet acquired by Teva) filed a lawsuit in the District of Delaware alleging patent infringement against Mylan based on Mylan's ANDA to manufacture and sell a generic version of the pharmaceutical product Nuvigil (armodafinil).[116]

135. Cephalon sued six other generic manufacturers, along with Mylan, who were seeking ANDA approval to manufacture and sell armodafinil tablets.[117]

136. Cephalon's patents asserted in the suit were weak and Cephalon was so unlikely to succeed on its patent infringement claims that a reasonable, competent, and experienced patent attorney would have given Cephalon only a 20% chance of prevailing.[118]

137. In December 2010, the Judicial Panel on Multi-District Litigation consolidated the cases into a multidistrict litigation in the District of Delaware before the Honorable Gregory M. Sleet.[119]

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[115] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 11, 2016) at 64, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/64b7ff41-922a-4b39-afa6-27d50cd5adc9.pdf.

[116] *See generally*, Complaint, *Cephalon, Inc. v. Mylan Pharms., Inc.*, No. 1:09-cv-00954 (D. Del. Dec. 11, 2009), ECF No. 1; *see also In re EpiPen MDL*, 545 F. Supp. 3d 922, 958 (D. Kan. 2021).

[117] *See* Transfer Order at Schedule A, *In re Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Dec. 8, 2010), ECF No. 1; *In re EpiPen MDL*, 545 F. Supp. 3d at 959.

[118] *In re EpiPen MDL*, 545 F. Supp. 3d. at 999.

[119] *Id.; In re EpiPen MDL*, 545 F. Supp. 3d at 959.

138. In the Armodafinil Patent Litigation MDL, the Nuvigil defendants advanced similar defenses and relied on the same experts.[120]

139. In October 2011, while the Nuvigil litigation was pending, Teva acquired Cephalon.[121]

140. After Cephalon filed the Nuvigil lawsuits, the Hatch-Waxman Act triggered a 30-month stay for each Nuvigil defendant's ANDA, meaning the FDA couldn't finally approve those ANDAs while the Nuvigil litigation was ongoing.[122]

141. But, during the 30-month stay, the FDA had tentatively approved Mylan's ANDA, which meant that the ANDA met substantive requirements for final approval.[123]

142. Mylan's stay was set to expire on May 3, 2012, which meant that the FDA potentially could have granted final approval on that day.[124] The FDA did grant final approval soon after on June 1, 2012.

143. Teva continued to litigate the Nuvigil litigation as Cephalon even after it acquired Cephalon.[125] This complaint refers to Cephalon as Teva going forward.

144. Teva asserted in a brief seeking a temporary restraining order and a preliminary injunction, filed in the Nuvigil litigation that: "Other than this patent

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[120] *In re EpiPen MDL*, 545 F. Supp. 3d at 959.
[121] *Id.*
[122] *Id.* at 959.
[123] *Id.*
[124] *Id.*
[125] *Id.* at n.33.

litigation, there are likely to be no legal impediments to Mylan's launching of its products on or after May 3[, 2012]."[126]

145. Mylan refused to agree to forgo launching its product on May 3, 2012.[127]

3. Teva, Pfizer, and Mylan agree to a trade-for-delay scheme to settle the Nuvigil litigation.

146. On March 30, 2012, as the parties were in settlement negotiations over both the Nuvigil and EpiPen patent litigations, Mylan rejected Teva's request to extend the stay on it entering the generic market for Nuvigil until May 15, 2012.[128]

147. The next day, Teva sent a draft term sheet to Mylan.[129]

148. On April 26, 2012, Mylan and Teva executed a binding term sheet to resolve the claims against Mylan in the Nuvigil litigation.[130]

149. This was the same day that Pfizer and Teva executed a binding term sheet that resolved the Teva/EpiPen litigation.[131]

150. Under the agreement to resolve the Nuvigil litigation, Mylan acquired the right to launch certain armodafinil products on June 1, 2016 (50mg, 150mg, and 250mg strength tablets) and others on June 1, 2019 (100mg and 200mg strength tablets) without infringing Teva's patents, which were set to expire in 2024.[132]

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[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.* at 960.
[131] *Id.*
[132] *Id.*

151. The settlement did not include any monetary payment between Mylan and Teva.[133]

152. The other generic competitor defendants in the Nuvigil MDL went to trial in July 2012, and Teva prevailed. But the generic defendants appealed.[134] After oral argument, but while the appeal was pending, the parties settled. In those settlements, Teva agreed to pay the generic defendants millions of dollars, even though it was Teva that won at trial.[135] Those settlements indicate that Teva knew its Nuvigil infringement claims were weak and expected the trial court's decision to be reversed.

153. Because Teva didn't have a strong chance of prevailing in the Nuvigil litigation, Mylan's agreement to delay entry into the generic Nuvigil market until 2016 represented valuable compensation amounting to a reverse payment settlement made in exchange for the EpiPen settlement. That conclusion is consistent with the EpiPen and Nuvigil agreements being negotiated as a package deal.

154. Then-President and CEO of Teva William Marth had discussions with Mylan CEO Heather Bresch about both the Teva/EpiPen settlement and the Nuvigil settlement.[136]

155. In those discussions, Mr. Marth had "talked to Heather . . . about settlement" of the EpiPen litigation and that "[s]he (Heather) wants to give us a 2018 entry date but would likely agree to 2017" and noting that "[j]ointly but not directly connected is the

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[133] *Id.*
[134] *Id.*
[135] *Id.; see also id.* at 999-1000.
[136] *Id.* at 961.

Nuvigil litigation" where Mr. Marth "offered a 2018 entry date."[137] Further communication also revealed that in the first email that "Bill [Marth] got a call from Heather at Mylan" and asking what "exactly did we propose re epi and nuvigil?" and responding in another email with "2014 for epi and 2018 for nuvigil. No months specified."[138] Finally, those discussions culminated in sending the Nuvigil term sheet and discussing changes that were "agreed to between Heather and Mr. Marth."[139]

156. Also, other Mylan and Teva employees discussed the EpiPen and Nuvigil settlements in the same communications, for example when Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018"[140] and noting that "the signed Nuvigil deal was" complete and "language w Pfizer on Epipen is done."[141] Further, Mylan employees emailing with the subject line "Epipen—Teva/Potential Settlement" and attaching a "Nuvigil Settlement DRAFT."[142]

157. On April 30, 2012, Mylan issued a press release announcing the Nuvigil settlement.[143] The press release left out that Mylan entered the Nuvigil settlement in return for Teva's agreement to the EpiPen settlement.

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[137] *Id.*
[138] *Id.* at 960-61.
[139] *Id.* at 961.
[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*

158. On May 10, 2012, Mylan's outside counsel sent a letter to the FTC and DOJ providing copies of the Nuvigil Settlement and EpiPen Settlement agreements.[144] The letter stated: "While Mylan does not believe it is required to file the EpiPen Settlement in connection with the Nuvigil Settlement, it nonetheless files this agreement as a potentially 'related' agreement solely out of an abundance of caution."[145] Mylan kept its letter to the FTC and DOJ confidential and the letter's contents were not publicly disclosed until June 23, 2021, when it was discussed in a public judicial opinion.[146]

159. On July 3, 2012, the FTC responded, noting that its "Bureau of Competition is concerned that the Teva-Mylan agreement on [another drug product,] generic Provigil[,] may be related to delayed generic Nuvigil entry and/or delayed generic EpiPen entry."[147]

160. A few years later, in May 2015, the FTC announced that it had "entered into a landmark settlement with Cephalon, Inc. and its parent company, Teva . . . to resolve its action against Cephalon for illegally monopolizing the market for the sale of its blockbuster sleep-disorder drug Provigil."[148] The settlement required Teva to pay $1.2 billion and was for conduct prior to Nuvigil.[149]

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[144] *Id.*
[145] *Id.*
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics*, Federal Trade Commission (May 28, 2015), https://www.ftc.gov/news-events/news/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill-gotten-gains-relinquished-refunds-will.

161. The FTC said it "was prepared to prove that Cephalon paid four generic competitors to abandon their challenges to Cephalon's Provigil patent and stay off the market for six years in violation of the antitrust laws, resulting in significantly higher prices for the drug and substantial consumer harm."[150]

162. Then, in February 2017, Mylan "agreed to pay $96.5 million to settle claims by drug purchasers that it delayed launching a generic version of Cephalon Inc.'s narcolepsy drug Provigil in exchange for payment from Cephalon."[151]

163. And, in January 2017, Mylan reported that it had "received a 'preliminary' inquiry from" the FTC "asking about the company's commercial practices for its EpiPen severe-allergy treatments."[152]

164. Mylan's representation to the FTC in 2012 that it was not required to file the settlements together and that it only did so "out of an abundance of caution" was intended to prevent and/or delay any subsequent investigation into the agreements. The FTC's landmark settlement with Teva and Cephalon over the illegal monopolization of the sleep-disorder market with Provigil indicates that, had Mylan accurately represented that the two settlements were in fact negotiated as a package deal, the resulting FTC investigation and additional scrutiny likely would have prevented the deal from being approved and led to generic EpiPen and Nuvigil entry much, much sooner than ultimately occurred.

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[150] *In re EpiPen MDL*, 545 F. Supp. 3d at 961.
[151] *Id.* at 961-62.
[152] *Id.* at 962.

165. As a result of the conspirators' scheme to delay the entry of Mylan's generic version of Nuvigil, patients and payors in all 50 states were prevented from obtaining a less expensive, bioequivalent version of Nuvigil and instead, in every state, patients and payors paid millions of dollars more in supracompetitive and artificially-high prices for brand Nuvigil.

4. Teva's Nuvigil sales collapse after Mylan's generic hits the market.

166. On June 1, 2016, Mylan's delayed Nuvigil generic finally hit the market, four years after it received FDA approval.[153]

167. That same year, in 2016, Teva's revenue realized from Nuvigil sales decreased 46%, from $373 million to $200 million.[154]

168. Teva stated that the decrease in 2016 Nuvigil revenue was "due to generic competition beginning in 2016, when Mylan started to sell its generic version of Nuvigil in the United States pursuant to an agreement with us."[155]

[153] Mylan N.V., *Mylan Launches First Generic of Nuvigil® Tablets*, (June 1, 2016), https://investor.mylan.com/news-releases/news-release-details/mylan-launches-first-generic-nuvigilr-tablets.

[154] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 15, 2017) at 69, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/c29d340b-f8f6-47f2-91e3-5757455569de.pdf.

[155] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 15, 2017) at 70, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/c29d340b-f8f6-47f2-91e3-5757455569de.pdf.

169. In December 2016, "six additional [generic] competitors entered the market, including Teva's authorized generic product, further reducing [Teva's Nuvigil] sales."[156] It was not until these additional generic competitors entered the market that there was full price competition for brand and generic forms of Nuvigil.

170. That next year, 2017, Teva's revenue realized from Nuvigil sales decreased 70%, from $200 million to $61 million.[157]

171. Teva explained that the decrease in 2017 Nuvigil revenue was "mainly due to generic competition."[158]

172. Teva ceased reporting Nuvigil revenue after 2017.

RELEVANT MARKET

173. The relevant market in this case is the market for armodafinil products; the market for EAI injectors is also relevant to the extent Mylan and Pfizer obtained prolonged exclusivity in that market through the challenged scheme.

174. By the trade for delay scheme, Teva enabled Mylan and Pfizer's prolonged monopolization of the market for epinephrine auto-injectors ("EAI market"). There were

[156] Teva Pharm. Indus., Ltd., Annual and Transition Report (Form 20-F) (Feb. 15, 2017) at 70, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/c29d340b-f8f6-47f2-91e3-5757455569de.pdf.

[157] Teva Pharm. Indus., Ltd., Annual Form (Form 10-K) (Feb. 12, 2018) at 68-69, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/34f4566e-3db2-4a13-b29c-05522b6fd675.pdf.

[158] Teva Pharm. Indus., Ltd., Annual Form (Form 10-K) (Feb. 12, 2018) at 69, https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/34f4566e-3db2-4a13-b29c-05522b6fd675.pdf.

no reasonably interchangeable drug products that were available to prescribing physicians for the indications for which EAIs were prescribed.

175. Mylan/Pfizer had monopoly power in the EAI market at all relevant times.

176. By the trade-for-delay scheme, Teva was able to prolong its monopolization of the market for armodafinil products ("armodafinil market"), this includes Nuvigil in all its forms and dosage strengths, and AB-rated bioequivalent versions of Nuvigil. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which armodafinil is prescribed.

177. Teva had monopoly power in the armodafinil market at all relevant times.

178. The relevant geographic market is the United States and its territories.

CLASS ACTION ALLEGATIONS

179. Plaintiffs repeat and re-allege every allegation above as if set forth in full here.

180. **Nuvigil Nationwide Class:** Pursuant to Federal Rule 23(b)(3), Plaintiffs bring this suit on their own behalf and on behalf of a proposed national class of all other similarly situated persons ("**Nuvigil Nationwide Class**") consisting of:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all the purchase price for Nuvigil, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period June 1, 2012 through December 31, 2017 (the "Nuvigil Class Period"). For purposes

of the Class definition, persons or entities "purchased" Nuvigil if they paid or reimbursed some or all the purchase price.

Excluded from the Nuvigil Nationwide Class are:

a. The Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. Governmental entities, except for government funded employee benefit plans;

c. The judges in this case and any members of their immediate families;

d. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and

e. All persons who are currently incarcerated.

181. **Nuvigil State Law Class:** Pursuant to Federal Rule 23(b)(3), Plaintiffs bring this suit on their own behalf and on behalf of a proposed class of all other similarly situated persons ("**Nuvigil State Law Class**") consisting of:

All persons or entities in the Indirect Purchaser States who purchased and/or paid for some or all the purchase price for Nuvigil, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period June 1, 2012 through December 31, 2017 (the "Nuvigil Class Period"). For purposes of the Class definition, persons or entities "purchased" Nuvigil if they paid or reimbursed some or all the purchase price.

Excluded from the Nuvigil State Law Class are:

a. The Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. Governmental entities, except for government funded employee benefit plans;

c. The judges in this case and any members of their immediate families;

d. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and

e. All persons who are currently incarcerated.

182. The Classes consist of millions of purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class Members before the Court.

183. Under Rule 23(b)(3), there are numerous and substantial questions of law or fact common to all the members of the Classes and which predominate over any individual issues. Included within the common question of law or fact are:

a. The definition of the relevant product market;

b. Teva's and Mylan's market power;

c. Whether Teva and Mylan monopolized and continue to monopolize the relevant product markets using anticompetitive behavior;

d. Whether Teva and Mylan attempted to monopolize and continue to attempt to monopolize the relevant product markets using anticompetitive behavior;

e. Whether Teva's, Mylan's, and Pfizer's conduct constitutes an unreasonable restraint of trade;

f. Whether the EpiPen/Nuvigil Enterprise engaged in a pattern of racketeering;

g. Whether Teva and Mylan unlawfully maintained monopoly power through all or part of their overall anticompetitive scheme;

h. Whether Teva's and Mylan's anticompetitive scheme suppressed generic EpiPen products, Nuvigil products, or other competing products;

i. Whether the EpiPen/Nuvigil Trade-for-Delay Scheme, in whole or in part, has substantially affected interstate and intrastate commerce; and

j. The quantum of overcharges paid by the Classes in the aggregate.

184. The claims of the Plaintiffs are typical of the claims of the respective Class Members, in that they share the facts above and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiffs and Defendant's conduct affecting Class Members, and Plaintiffs have no interests adverse to the interests of other Class Members.

185. Plaintiffs will fairly and adequately protect the interests of Class Members and have retained counsel experienced and competent in the prosecution of complex class actions including complex questions that arise in antitrust and RICO litigation.

186. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method of adjudication of all claims asserted is more efficient and manageable for at least the following reasons:

a. The liability claims presented in this case predominate over any questions of law or fact, if any exist at all, affecting any individual member of the Classes;

b. Absent certification of the Classes, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;

c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;

d. When the liability of Defendants has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and

e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by

which Plaintiffs and Class Members can seek redress for the harm caused to them by Defendants.

187. Because Plaintiffs seek relief for the entire Classes, the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members, which would establish incompatible standards of conduct for Defendants.

188. Further, bringing individual claims would overburden the courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Classes would, as a practical matter, be dispositive of the interest of other members of the Classes who are not parties to the adjudication and may impair or impede their ability to protect their interests. Consequently, class treatment is a superior method for adjudication of the issues in this case.

ANTITRUST INJURY

189. Defendants' anticompetitive conduct had the following effects, among others:

a. Price competition has been restrained or eliminated with respect to armodafinil;

b. The price of armodafinil being fixed, raised, stabilized, or maintained at artificially inflated levels;

c. Purchasers of armodafinil have been deprived of free and open competition; and

d. Purchasers of armodafinil, including Plaintiffs, paid artificially inflated prices.

190. The purpose of Defendants' conduct was to exclude competition and raise, fix, or maintain the price of armodafinil against generic equivalents. As a direct and foreseeable result, Plaintiffs and the Classes paid supracompetitive prices for armodafinil during the Class Periods.

191. By reason of the alleged violations of the antitrust laws, Plaintiffs and the Classes have sustained injury to their businesses or property, having paid higher prices for armodafinil than they would have paid in the absence of Defendants' illegal conduct, and as a result have suffered damages.

192. This is an antitrust injury of the type that the antitrust laws were meant to punish and prevent.

EQUITABLE TOLLING, DISCOVERY RULE, AND FRAUDULENT CONCEALMENT

193. At all times relevant to this Complaint, Teva took active steps to conceal its unlawful activities, including through the combination or conspiracy alleged. For example, Teva and its co-conspirators concealed their exchange of generic entry dates. Additionally, on May 10, 2012, Mylan reported those settlements to the DOJ as unrelated: "While Mylan does not believe it is required to file the EpiPen Settlement in connection with the Nuvigil Settlement, it nonetheless files this agreement as a potentially 'related'

agreement solely out of an abundance of caution."[159] And even though the two settlements were negotiated in conjunction and signed the **same day** (April 26, 2012)[160], the conspirators announced the two settlements separately over the course of multiple days to conceal the fact that each settlement was consideration for the other.

194. The parties to the two settlements kept the actual settlement documents confidential, resisted their production in subsequent litigation over the EpiPen, and then marked them CONFIDENTIAL, preventing members of the public from seeing them.

195. Teva's later settlement agreements with other potential generic entrants for Nuvigil remain confidential and unavailable to the public.

196. **Discovery Rule**: Plaintiffs and the members of the Classes had no knowledge of the alleged conspiracy, or of facts sufficient to place them on inquiry notice of the claims set forth.

197. Information in the public domain was insufficient to place Plaintiffs and members of the Classes on inquiry notice of Teva's unlawful activities. Further, Plaintiffs and the members of the Classes had no means of obtaining any facts or information concerning Teva's unlawful, anticompetitive, unfair, and deceptive activities alleged, all of which were purposefully concealed by Defendants.

198. For these reasons, even if a statute of limitations did apply, the claims of Plaintiffs and the Classes did not begin to run and have been tolled.

[159] *In re EpiPen MDL*, 545 F. Supp. 3d at 961.
[160] *Id.* at 960.

199. **Fraudulent Concealment:** The statutes of limitation were further tolled by the doctrine of fraudulent concealment. Teva's anticompetitive agreements were self-concealing and Teva also actively concealed the existence of its illegal scheme, including through false or misleading representations. The conspirators also intentionally concealed the actual documents for the key settlement agreements and did everything possible to prevent crucial details of those documents from becoming public. Accordingly, it was not until mid-2021 that the facts that the two settlements were entered into simultaneously and that they were negotiated together as package deal were made public in filings in the EpiPens MDL before this Court.

200. In addition, and unlike traditional settlement negotiations in litigation, the EpiPen and Nuvigil package settlement was negotiated over the phone and no proposals were exchanged in writing, indicating that Mylan and Teva did not want to leave a paper trail for their quid pro quo deal.

201. Plaintiffs exercised appropriate due diligence under the circumstances. Thus, Plaintiffs lacked the ability to discover that the drug prices it was paying were *higher than they should have been* because of anticompetitive, fraudulent, or otherwise deceptive conduct.

202. Drug prices can increase for a variety of reasons, and no information available to Plaintiffs alerted it to Teva's fraudulent, anticompetitive, unfair, and deceptive conduct and the effects it had on Nuvigil or EpiPen prices.

203. **Continuing Tort:** Plaintiffs' claims accrue each time they suffered injury as a result of Teva's conduct. Plaintiffs suffered injury each time they paid prices for Nuvigil or EpiPens that were higher than they would have paid for generic alternatives absent Teva's anticompetitive conduct. Each sale of branded Nuvigil or EpiPens at artificially inflated prices constitutes an overt act in furtherance of Teva's continuing anticompetitive scheme.

204. As a result, Defendants are estopped from relying on any statute of limitations defense because their illegal, anticompetitive, deceptive, and fraudulent practices, as alleged, which are continuing, have created continuing and repeated injuries to Plaintiffs and the Classes.

CLAIMS FOR RELIEF

COUNT I

Violation of Sections 1 & 2 of the Sherman Act (15 U.S.C. §§ 1-2)
Regarding Nuvigil Against All Defendants
(on behalf of Plaintiffs and the Nuvigil Nationwide Class)

205. The allegations set forth above and below are incorporated here by reference.

206. Plaintiffs bring this case under §§ 1 and 2 of the Sherman Act individually and on behalf of the Nuvigil Nationwide Class.

207. The relevant market for Nuvigil is the United States market for brand or generic armodafinil ("armodafinil market").

208. At all relevant times, Defendants possessed substantial market power (*i.e.*, monopoly power) in the armodafinil market. Defendants possessed the power to control

prices in, prevent prices from falling in, and exclude competitors from the armodafinil market.

209. Defendants' conscious objective was to unreasonably restrain trade and maintain their monopoly in the armodafinil market through the overarching anticompetitive scheme to block and delay market entry of competing generics.

210. By their unlawful agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in the armodafinil market in a per se violation of § 1 of the Sherman Act (15 U.S.C. § 1).

211. Through the overarching anticompetitive scheme, as alleged extensively above, Defendants conspired to monopolize and did wrongfully and intentionally maintain monopoly power in the armodafinil market in violation of § 2 of the Sherman Act (15 U.S.C. § 2).

212. Plaintiffs and members of the Nuvigil Nationwide Class indirectly purchased substantial amounts of Nuvigil from Defendants.

213. Had manufacturers of competing Nuvigil generics entered the market and competed with Nuvigil in a timely fashion, Plaintiffs and other members of the Nuvigil Nationwide Class would have substituted lower-priced competing products for the higher-priced brand name Nuvigil for some or all their requirements, and/or would have paid lower net prices on their remaining Nuvigil purchases.

214. As a result of Defendants' unreasonable restraint of trade and unlawful maintenance of monopoly power in the armodafinil market, Plaintiffs and members of the

Nuvigil Nationwide Class were harmed by paying artificially inflated and supracompetitive prices.

215. Plaintiffs and the Nuvigil Nationwide Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates §§ 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2).

COUNT II

Conspiracy and Combination in Restraint of Trade Under State Law Regarding Nuvigil Against All Defendants

(on behalf of Plaintiffs and the Nuvigil State Law Class)

216. The allegations set forth above are incorporated here by reference.

217. Defendants knowingly engaged in an anti-competitive scheme designed to delay and block entry of generic competition to Nuvigil. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Nuvigil.

218. Beginning in 2012 with the settlement of the Nuvigil patent litigation, Defendants engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to prevent the sale of a generic version of Nuvigil in the United States, thereby protecting Nuvigil from any generic competition for at least four years.

219. But for the illegal agreement about Nuvigil, Mylan and other generic drug manufacturers would have begun marketing generic versions of Nuvigil well before the 2016 delayed entry date it agreed to.

220. Defendants' illegal agreement with Mylan about Nuvigil covered a sufficiently substantial percentage of the armodafinil market to harm competition.

221. Defendants engaged in unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below.

222. There was a gross disparity between the price that Plaintiffs and the Nuvigil State Law Class members paid for Nuvigil and the value received, given that a less expensive substitute generic product should have been available.

223. As a direct and proximate result of Defendants' unfair competition or unfair or unconscionable acts or practices in violation of the state consumer protection statutes listed below, Plaintiffs and the Class were deprived of the opportunity to purchase a generic version of Nuvigil and forced to payer higher brand prices.

224. By engaging in the foregoing conduct, Defendants violated the following state laws:

a. California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*);

b. The California Cartwright Act (Cal. Bus. & Prof. Code § 16700, *et seq.*).

225. Plaintiff and the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of:

(1) being denied the opportunity to purchase lower-priced generic Nuvigil and (2) paying higher prices for Nuvigil than they would have but for Defendants' conduct. These injuries are of the type that the laws of the States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from what makes Defendants' conduct unlawful.

226. Plaintiffs and the Nuvigil State Law Class seek damages, damages multipliers, and attorney fees as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT III

Monopolization and Monopolistic Scheme Under State Law Regarding Nuvigil Against All Defendants

(on behalf of Plaintiffs and the Nuvigil State Law Class)

227. The allegations set forth above and below are incorporated here by reference.

228. Through the overarching anticompetitive scheme, as alleged extensively above, Defendants willfully maintained their monopoly power in the armodafinil market using restrictive or exclusionary conduct, rather than by greater business acumen.

229. As a direct and proximate result of Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiffs and the Nuvigil State Law Class were injured.

230. To the extent Defendants are permitted to assert any, there is and was no cognizable, non-pretextual procompetitive justifications for their actions comprising the anticompetitive scheme that outweigh the scheme's harmful effects.

231. Even if there were some conceivable justifications that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

232. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully maintained their monopoly power in the armodafinil market in violation of the following state antitrust laws:

a. California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*);

b. The California Cartwright Act (Cal. Bus. & Prof. Code § 16700, *et seq.*).

233. Plaintiffs and the Nuvigil State Law Class seek damages, damages multipliers, and attorney fees as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT IV

Violation of The Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c) and (d)

(on behalf of Plaintiffs and Nuvigil Nationwide Class)

234. The allegations set forth above and below are incorporated here by reference.

235. Plaintiffs bring this Count on behalf of the Nuvigil Nationwide Class against all Defendants. Section 1962(c) of the RICO Act makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C.

§ 1962(c). Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d). Plaintiffs pursue both subsections (c) and (d) against each of the Teva Defendants.

236. This Count seeks to hold Defendants accountable for engaging in a scheme to defraud with Mylan and Pfizer (thereby forming a RICO association in fact enterprise) to accomplish a long-range pattern of wire fraud that caused major financial damages to consumers and payers, who were forced to overpay several hundreds of millions of dollars for Nuvigil and the EpiPen.

237. These overcharges occurred only because the generic versions of both brand products were illegally suppressed through deception, false statements, fraudulent omissions, half-truths, and fraudulent concealment, which the Ninth Circuit has recognized are all actionable forms of wire fraud. It is not required for a plaintiff to plead wire fraud based only on false statements; the scope of wire fraud is far broader, and the focus of wire fraud is the scheme to defraud.

238. It is well established that generic competition quickly takes over 90% of market share of a brand drug, and the price for generic drugs is substantially lower. Thus, for a company with a brand product, the prospect of generic competition is catastrophic. Generic drugs are safe, effective, equivalent, and automatically substituted by pharmacists based on state laws, and all 50 states have generic substitution laws. Combined, this means that generic competition effectively wipes out a brand company's high margins on branded drugs, including Nuvigil or the EpiPen.

239. As two of the largest generic drug companies, Teva and Mylan were intimately aware of how this price erosion works and the effects of generic competition on a brand drug/device. Thus, by engaging in their schemes to suppress generic competition, Teva and Mylan in particular acted willfully and with the specific intent to defraud payers.

240. Although Pfizer (which manufactured the EpiPen) was a major brand drug company in or around 2012, Mylan and Teva were not. To the contrary, both were primarily generic drug companies making low margins on thousands of generic drugs.

241. But both companies had a way out of these low margins: both had rights to make massive revenues from at least one highly profitable specialty drug/device: Nuvigil (for Teva) and the EpiPen (Mylan).

242. At the same time, both Teva and Mylan were about to launch competing generic drugs against each other's specialty products. Instead of competing, however, they decided to collude and conspire to secretly agree to make their competing claims go away in exchange for an agreement not to launch competing generic drugs. They knew this scheme was illegal and they took great care to camouflage and not make public their secret, behind the scenes efforts.

243. At all relevant times, Defendants have been "persons" under 18 U.S.C. § 1961(3).

244. For many years, Defendants, the Mylan entities, and the Pfizer entities aggressively sought to use all means to maintain exclusive control of their exclusive

monopolies in the EAI and armodafinil markets in the United States. Finding it impossible to achieve their ambitious goals lawfully, however, Defendants, the Mylan entities, and the Pfizer entities resorted to cheating through their fraudulent scheme and RICO conspiracy.

245. Since early 2012, likely beginning in January and maybe even in late 2011, Defendants, the Mylan entities, and the Pfizer entities worked together to manipulate the markets for EAIs and armodafinil as an association-in-fact enterprise, whose activities have affected interstate commerce.

246. These entities all participated directly or indirectly in a scheme to suppress generic competition in the EAI and armodafinil markets (the "Generic Suppression Enterprise").

247. The common purpose of the enterprise was to increase revenues and to fraudulently cause payers and consumers to purchase EpiPen devices and Nuvigil products when a generic version of these products could have been on the market if not for the suppression. As part of their scheme, Defendants also misled and deceived the FDA and the federal courts regarding the legitimacy of their settlement agreements and did not disclose that Mylan, Pfizer, and Teva were conspiring to not compete and to block generic drugs that would have saved purchasers hundreds of millions of dollars in charges every year. Had Teva, Mylan, and Pfizer disclosed publicly what they secretly agreed to privately, their scheme would have been exposed, the courts would not have approved their settlements, and their executives would have faced criminal scrutiny from

prosecutors. The efforts to conceal their activities and to avoid stating publicly what they were communicating secretly in private confirm they were aware of the illegality of their activities.

248. The longevity of the enterprise and the relationships formed among Teva, Mylan, and Pfizer were ongoing and long-term. That Marth and Bresch, the CEOs of Teva North America and Mylan, were personally calling each other on cell phones proves that these two executives were closely related and comfortable allocating markets. To be clear, as set forth below and as confirmed by Defendants' own emails, the scheme to defraud was orchestrated and carried out by these two top American executives of Teva and Mylan.

249. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants, the Mylan entities, and the Pfizer entities illegally extracted revenues of hundreds of millions of dollars from Plaintiffs and the Classes. As explained below, the years-long misconduct of Defendants violated RICO Sections §§ 1962(c) and (d).

A. The Nuvigil/EpiPen Generic Suppression Enterprise

250. Defendants, the Mylan entities, and the Pfizer entities operated or managed the affairs of the Generic Suppression Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

251. At all relevant times, Defendants, the Mylan entities, and the Pfizer entities operated as an association-in-fact enterprise, which was formed to engage in a scheme to

defraud payers, consumers, regulators, and the courts regarding the availability of generic alternatives in the EAI and armodafinil markets and their successful efforts to suppress that generic competition.

252. Each of the Teva Defendants is a "person" under 18 U.S.C. § 1961(3).

253. The Teva Defendants operated and managed the Generic Suppression Enterprise to artificially increase Nuvigil and EpiPen sales and revenue and to enrich Teva and its top executives.

254. Marth became the CEO of Teva's domestic entity, Teva North America, in January 2008. Prior to that, he was President and Chief Executive Officer of Teva USA. As Teva announced in January 2008 when Marth was promoted to CEO of Teva North America:

> Mr. Marth, age 53, who has 30 years experience in the pharmaceutical industry and close to a decade with Teva, will be responsible for North America, including the U.S. Mr. Marth has run the U.S. generics business where he has handled much of the day-to-day commercial activities since his appointment as EVP in 2002 and has been President and Chief Executive Officer of Teva USA since 2005. He has overseen a number of significant product launches, most notably the December launch of generic Protonix, and two of the largest launches in the history of U.S. generics, Simvastatin and Pravastatin in 2006. Mr. Marth, will continue to be based in Teva's North

American headquarters in North Wales, PA and will report directly to Teva President and CEO, Shlomo Yanai.[161]

255. Marth was deeply involved in the day-to-day activities while at Teva and rose throughout numerous positions at Teva. He was identified as a "key strategist in establishing Teva as a leading Specialty Pharmaceutical Company"[162] in the United States:

William Marth became President and CEO of Albany Molecular Research. in January 2014, after briefly serving as the company's non-executive Chairman. In 2013, Mr Marth served as a senior advisor to Teva Pharmaceuticals following his retirement in 2012 as President and Chief Executive Officer of Teva – Americas. He had previously served as President and Chief Executive Officer of Teva North America from January 2008 to June 2010, as President and Chief Executive Officer of Teva USA from January 2005 to January 2008 and Executive Vice President and Vice President of Sales and Marketing for Teva USA. In addition Bill worked with several large equity firms providing guidance on their healthcare investments.

Mr Marth was a key strategist in establishing Teva as a leading Specialty Pharmaceutical Company and being ultimately recognized as the leading worldwide producer of generic drugs. Responsibilities include heading the respiratory, neuroscience, oncology and women's healthcare divisions plus Select Brands. He was a member of Teva's global executive management team and Teva Americas' board of directors from 2007 to 2012.

Prior to joining Teva USA, he held various positions with the Apothecon division of Bristol-Myers Squibb.

256. It is true that Teva had some specialty products. But it was also the primary generic drug manufacturer in the world at the time of the conduct at issue. And as a generics company, Teva typically makes low margins on drug sales. Nuvigil, a specialty branded drug, was atypical for Teva to manufacture and to sell, and it represented a unique, highly profitable revenue stream for Teva. Recognizing this opportunity, Marth and other

[161] *Teva Announces Departure Of North American Ceo, William S. Marth To Become Ceo Of Teva North America*, Fierce Biotech (January 10, 2008, 11:00 am), https://www.fiercebiotech.com/biotech/teva-announces-departure-of-north-american-ceo-william-s-marth-to-become-ceo-of-teva-north

[162] *William Marth*, The Pharma Letter, https://www.thepharmaletter.com/profile/william-marth

executives decided to exploit Nuvigil to generate hundreds of millions of dollars in illegal revenue for Teva.

257. As to the Mylan entities, Mylan N.V. and Mylan Specialty L.P. were each distinct legal entities at the time of the conduct in question. All the Mylan entities were either dissolved or acquired as part of a merger and are now known as Viatris. Because these entities are not defendants here, they are still called the "Mylan entities" for clarity and simplicity.

258. Along with Teva, Mylan was a major generic drug company. As such, like Teva, it made low margins on drug sales and was on the hunt for higher margins and revenue. Like Nuvigil, the EpiPen, a specialty branded drug, was atypical for Mylan to sell and represented a unique, highly profitable revenue stream for Mylan.

259. Mylan N.V., through Bresch, was directly involved in nearly all of the sales, pricing, and marketing decisions regarding EpiPens, as catalogued above. Mylan Specialty, LP, was the primary entity that marketed, distributed, and sold the EpiPen. The Mylan entities operated or managed the affairs of the Generic Suppression Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c), including wire fraud and mail fraud.

260. As to the Pfizer entities, Pfizer, Inc., King Pharmaceuticals, LLC, and Meridian Medical Technologies, Inc. were responsible for manufacturing the EpiPen, and the Pfizer entities participated in the scheme to suppress generic competition to the EpiPen and the pay-for-delay settlement agreements. The Pfizer entities operated or managed the

affairs of the Generic Suppression Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c), including wire fraud and mail fraud.

261. Teva, on one hand, and Mylan and Pfizer, on the other, are competitors in selling products. They should not be conspiring to allocate markets and stop generic competition for competing products, and they knew that what they were doing to block generic competition was illegal. They also did not disclose any of their secret agreements when they filed legal documents (using the wires) in federal court to dismiss the pending patent litigation over the products at issue.

262. On top of this, such legal documents could not have been filed but for each of Defendants', the Mylan entities', and the Pfizer entities' retention and use of lawyers and law firms to facilitate and paper over the fraud. On information and belief, such lawyers and law firms were paid money (using the wires) by Defendants, the Mylan entities, and the Pfizer entities to implement, give legitimacy to, and conceal this Generic Suppression Enterprise. Likewise, Teva's in-house counsel willfully sent email communications that specifically revealed the dates that Teva agreed to forestall generic competition.

263. As discussed above, on April 26, 2012, Pfizer and Mylan jointly settled with Teva to sideline the generic competition to the EpiPen and Teva settled with Mylan to sideline the generic competition to Nuvigil.

264. The settlement agreements secretly restrained competition and ensured that the Generic Suppression Enterprise could successfully continue without the EpiPen facing

competition from Teva and Nuvigil facing competition from Mylan. These settlement agreements were exchanged through drafts numerous times by each of the lawyers representing Teva, Pfizer, and Mylan. On information and belief, the lawyers representing Teva, Pfizer, and Mylan were paid money for their services, including crafting, negotiating, and formulating such settlements in furtherance of the Generic Suppression Enterprise.

265. Each email and each telephone call sent or received in furtherance of this scheme is an act of wire fraud (and thus a separate predicate act under civil RICO). It is not required that the contents of any phone call or email be fraudulent. To the contrary, wire fraud reaches any email or phone call in furtherance of a scheme to defraud, regardless of the contents of the wire.

266. Moreover, each transmission of money by means of wire to the lawyers or law firms of Defendants, the Mylan entities, and the Pfizer entities is an act of wire fraud (and thus a separate predicate act under civil RICO) with the purpose of executing or furthering the Generic Suppression Enterprise.

267. Discovery is needed to uncover all the confidential communications sent between the law firms. Likewise, Teva, Mylan, and Pfizer routinely try to include lawyers in communications to conceal these communications behind the cloak of the attorney-client privilege. But communications with a lawyer are protected only if they relate to past crimes or frauds; the crime/fraud exception punctures any privilege for communications

that furthered ongoing criminal acts or ongoing fraud. As such, all the email, text message, and phone communications are fully discoverable here.

B. The Generic Suppression Enterprise Sought to Illegally Divide Two Lucrative Branded Markets and to Ensure Continued Monopoly Profits and Revenues by Forcing Consumers to Purchase Branded Products

268. At all relevant times, the Generic Suppression Enterprise had an existence separate and distinct from Defendants was separate and distinct from the pattern of racketeering in which Defendants engaged. It was an ongoing and continuing association of legal entities.

269. Each member of the Generic Suppression Enterprise shared in the financial windfall generated by the scheme to defraud, and each member shared in the common purpose of forcing consumers to purchase Nuvigil and the EpiPen at an inflated price as a brand, not a generic. This common purpose united all members of the Enterprise, even though they at times competed.

270. The Generic Suppression Enterprise engaged in, and its activities affected interstate and foreign commerce, because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement, and sale of Nuvigil and the EpiPen throughout the country, and the receipt of monies from the sale of the same.

271. Within the Generic Suppression Enterprise, there was a common communication network by which co-conspirators shared information regularly, as evidenced by the cell phone conversations between the CEOs of Mylan and Teva and the

extensive emails sent among Teva, Mylan, and Pfizer executives and lawyers (both in-house and outside counsel).

272. Through the Generic Suppression Enterprise, Defendants, the Mylan entities, and the Pfizer entities worked as a continuing unit to further the illegal scheme and their common purposes of increasing their revenues and market share and minimizing losses.

273. While Defendants, the Mylan entities, and the Pfizer entities participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

274. Each Defendant was acting primarily in the interests of the Enterprise, not its own interests, by agreeing to block generic competition for its competitor (Teva in the case of Mylan/Pfizer and Mylan/Pfizer in the case of Teva). Questions regarding an actor's motive require discovery to flesh out; when engaging in conduct, these entities and individuals do not log or document what their "motive" is. The "motive" is a legal or factual conclusion based on the underlying facts and evidence.

275. Intentionally left blank.

276. Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in the Defendants, the Mylan entities, and the Pfizer entities' exclusive control. A relaxed pleading standard applies to these

email communications under repeated Ninth Circuit civil RICO case law and further discovery is needed. Plaintiffs are required to have knowledge of any communications sent to them by Defendants; they are not expected to know about all communications between or among Defendants and their confederates.

C. The Pattern of Racketeering: Mail Fraud, Wire Fraud, and Corruption of an Official Proceeding

277. To carry out, or attempt to carry out the scheme to defraud, Defendants, the Mylan entities, and the Pfizer entities knowingly participated, directly or indirectly, in the conduct of the affairs of the Generic Suppression Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

278. Repeated acts of mail and wire fraud engaged in by Defendants, the Mylan entities, and the Pfizer entities are the predicate acts of racketeering (18 U.S.C. § 1961(1)). Defendants, the Mylan entities, and the Pfizer entities violated 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud) by using the interstate mail and wires in furtherance of a scheme to defraud American payers by forcing them to pay for a brand Nuvigil or brand EpiPen instead of a generic.

279. In furtherance of this scheme, Defendants used the interstate wires (which includes email, payment of money, money transfers, remissions via wire transfer, telephone calls, faxes, the distribution of electronic news and reports, and financial earnings calls) to communicate with each other, to devise, orchestrate, facilitate, fund, and

execute the scheme to defraud, to file the sham settlements of the patent litigation with the use of lawyers and law firms, to issue press releases, and to engage in earnings calls with investors. Defendants also used interstate mail or wires to send notice of the settlement agreements to the DOJ and FTC.

280. Defendants', the Mylan entities', and the Pfizer entities' use of the wires includes several examples, many of which are set forth in more detail in the factual allegations above and in the extensive factual discussion and exhibits cited in *In re EpiPen MDL*, 545 F. Supp. 3d at 950-63.[163] These examples include repeated email and telephone communications among and between Teva, Mylan, and Pfizer executives and their counsel both leading up to and following the 2012 settlement agreements. This Court catalogued many of the emails and phone calls that occurred between late 2011 and extended throughout 2012; repeatedly, the executives and lawyers for these entities engaged in extensive uses of the interstate wires to devise, orchestrate, execute, and cover up their scheme. They could not have committed the generic suppression they did without making such extensive use of the interstate wires; the executives and lawyers were in different cities and different states and used the interstate wires to commit interstate fraud. *See, e.g.*, *In re EpiPen MDL*, 545 F. Supp. 3d at 952-53, 961 (D. Kan. 2021) (noting that "**several documents** reference that Mylan's lawyers spoke with Teva and Pfizer about the

[163] Dozens of exhibits cited in this opinion catalogue the various phone calls and emails among Teva and Mylan/Pfizer executives that stretched from late 2011 throughout 2012. In turn, dozens of predicate acts are apparent and obvious from the exhibits and documents discussed in that summary judgment opinion.

settlement" and that "other Mylan and Teva employees discussed the EpiPen and Nuvigil settlements in the same communications") (emphasis added); *id.* (noting that Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018."). Furthermore, Defendants, the Mylan entities, and the Pfizer entities could not have committed the generic suppression they did without the use of lawyers and law firms in execution and furtherance of their scheme, which upon information and belief, such lawyers and law firms were paid via wire transfer—each transfer a separate predicate act.

281. On March 8, 2012, Marth (then-President and CEO of Teva-Americas) used the interstate wires regarding the EpiPen and Nuvigil scheme, as Marth had "talked to Heather yesterday throughout the afternoon and evening about settlement" and that "[s]he (Heather) wants to give [Teva] a 2018 entry date but would likely agree to 2017" and noting that "[j]ointly but not directly connected is the Nuvigil Litigation" where Marth "offered a 2018 entry date." *In re EpiPen MDL*, 545 F. Supp. 3d at 922, 953, 960. Each wire sent before and after this email—and it is clear that dozens of emails and telephone calls followed in the wake of this secret deal among the lawyers and executives of Teva and Mylan/Pfizer—is a separate predicate act.

282. As Marth's email confesses, he made multiple uses of the interstate wires to telephone Bresch on March 7, 2012. Each phone call on March 7 alone between Bresch and Marth (the heads of two major companies) was an independent use of the interstate

wires in furtherance of the scheme to defraud, and discovery is necessary to obtain the telephone records to confirm the number and extent of the telephone calls.

283. Over 56 times between March 11 and April 26, 2012, Pfizer lawyers/executives used interstate wires (emails and phone calls) schemed with Mylan lawyers/executives to resolve the EpiPen and Nuvigil litigations by using sham settlements with Teva. These settlement agreements were not adversarial, arms' length, good faith settlements; they were willfully collusive settlements known to be illegal. The exhibits underlying these communications are all part of the publicly filed summary judgment briefing and order entered in the EpiPen MDL.

284. These are only a few of many examples of the pattern of racketeering. The Mylan, Pfizer, and Teva lawyers engaged in repeated emails and filings of the settlement agreement drafts and final versions, and their coordination furthered the scheme to defraud.

285. On April 30, 2012, Teva circulated using the interstate wires a press release entitled, "Teva settles Nuvigil litigation with Mylan," that noted that "it" settled its Nuvigil litigation with Mylan.[164]

286. This April 30 press release was misleading, fraud by omission, and fraud by half truth because Teva omitted from this press release the fact that this settlement was collusively obtained in exchange for trading generic launch dates for the EpiPen.

[164] *See* Teva Settles Nuvigil Litigation With Mylan, BUSINESS WIRE, April 30, 2012, https://www.businesswire.com/news/home/20120430005983/en/Teva-settles-Nuvigil-litigation-with-Mylan.

287. Had Teva's press release accurately informed payers, regulators, prosecutors, the FDA, the DOJ, the FTC, the federal courts, and the media the full truth underlying the two settlement agreements and how they had been obtained, Teva's press release would have triggered a backlash that would have stopped the scheme to defraud from proceeding or would have limited it.

288. Instead, in this press release, Teva falsely suggested and implied that it had reached a good faith, adversarial settlement in patent litigation, which lulled all of the above parties to believe that this was a legitimate settlement between Mylan and Teva. By choosing to speak using the interstate wires to the public at large, Teva assumed a duty to speak truthfully and fully about the subject matter: the Nuvigil settlement. Teva was not required to issue this press release; its decision to do so was voluntary and motivated by self-gain.

289. Teva used its own resources and spent the time and money to issue this April 30 press release, so at the very least, it is a fact question whether this press release was material. Teva, however, is precluded from arguing that this press release is immaterial given that, at the time, it viewed the topic significant enough that it spent the time, energy, and money to create the press release and circulate it.

290. To be clear, it is unknown who read this April 30 press release, and that fact is not essential and not part of the causation alleged by Plaintiffs. This interstate wire was still sent in furtherance of the scheme to defraud and thus is a predicate act. And this press release shows that in Teva's own mind, Teva thought it was necessary to tell the public

that it had obtained this settlement with Mylan. By doing so, Teva acted willfully and with fraudulent intent to project a false legitimacy surrounding the settlement it obtained with Mylan and to lull those who saw it into believing the settlement was legitimate.

291. On or around September 21, 2016, Congress (the U.S. House) held a hearing devoted specifically to the rising price of the EpiPen and the mystery underlying it. In this September 2016 hearing, held in Washington D.C., the House members repeatedly pointed to the lack of any "generic" competition, with Chairperson Jason Chaffetz opening the hearing by discussing the fact that the EpiPen contains a generic drug and therefore should not cost $608. He continued to hammer the absence of a generic EpiPen and ask questions about the lack of any generic alternative, proving the materiality to Congress and others that the absence of a generic EpiPen was significant:

> **Chairman Chaffetz:** Explain to me, when you buy the generic version, what's the difference in the generic version?
>
> **Ms. BRESCH:** It will be the same product with epinephrine autoinjector on it. It will be the same product.
>
> **Chairman CHAFFETZ:** So suddenly it's $608. Now you're going to have a generic of the generic, and that's going to be $300?
>
> **Ms. BRESCH.** Yes.

292. Ms. Bresch was under oath at this hearing and swore to tell the truth, but she did not. Teva knew this, but her statements furthered the scheme it was part of, and it did not correct the record.

293. The FDA sought to alleviate fears by pointing out that "Mylan has recently publicly announced they also will offer an authorized generic version to be available in the near future." In this exchange, a House member (Mr. Mica) asked about the lack of a generic drug, and the FDA's Deputy Director (Mr. Throckmorton) made clear that the FDA and others were unaware of the secret scheme to block generic competition:

> **Mr. MICA.** Do you have under consideration, I guess it would be public knowledge, anyone producing, attempting to produce generic competition?
>
> **Dr. THROCKMORTON.** I think it's public knowledge that there are companies that are looking at that.
>
> **Mr. MICA.** Because we need to know. I mean, one way to bring the price down is to have competition. Wouldn't that be correct?
>
> **Dr. THROCKMORTON.** I think it's public knowledge that there are companies that are looking at that.

294. This testimony makes clear that the absence of generic competition was material to the United States Congress. This hearing was devoted entirely to the "rising price" of the EpiPen, yet at no point did Mylan, Pfizer, or Teva ever speak fully or truthfully regarding their scheme to defraud. They chose to make selective, misleading statements about the price of the EpiPen, but they never disclosed their scheme to forestall generic competition.

295. It was neither a coincidence nor the result of fierce competition in the free market that there was no generic competition available. Instead, Mylan could raise the

price of the EpiPen over 500% only because Teva, Mylan, and Pfizer had secretly schemed to cheat by blocking all generic competition. Their scheme was so tightly controlled and well-coordinated that even a multi-hour hearing held by the United States Congress could not ferret it out.

296. At this September 2021 hearing, Bresch testified that Mylan would offer "the first-ever generic of the EpiPen product," and she did so to take pressure off the scheme to defraud by Teva, Mylan, and Pfizer that was in effect at the time of this testimony.

297. In sum, the September 2016 hearing testimony was broadcast across the interstate wires, and it was foreseeable to Teva that the testimony would be circulated. This September 2016 hearing testimony shows the ongoing fraud scheme stretched from 2011 to 2016, the pattern of racketeering was open-ended, and the scheme to defraud required the ongoing agreement and collusion of Mylan, Teva, and Pfizer to keep it from being revealed to Congress, regulators, prosecutors, payers, the media, and the American public.

298. Had the full truth of Teva's fraud scheme been known at the time of this September 2016 hearing, then executives from Mylan (including Ms. Bresch, who was present and under oath at the hearing, sitting only feet away from the members of Congress), Teva, and Pfizer would have been investigated and likely indicted for their naked wire fraud.

D. Causation and Damages

299. By reason of their pattern of racketeering activity, Defendants have caused Plaintiffs and the Nuvigil Nationwide Class members injury in their business and/or property, in the form of overcharges for brand drugs that never would have been purchased because of the erosion caused by generic competition.

300. Had generic versions of the EpiPen and Nuvigil launched earlier, as they would have in the but-for world, consumers and payers would have purchased them. In doing so, they would have paid lower prices.

301. There is a direct line between the scheme to defraud through the use of litigation, lawyers, and law firms and the overcharges incurred by Plaintiffs and the Class. There is no class (consumers and payers) better situated to file suit.

302. In addition, Plaintiffs and the Class were the intended targets of the scheme to defraud, making them the direct targets. Defendants knew that their scheme to defraud would ultimately harm consumers and payers, the ones who ultimately pay for the drug.

303. To this end, Teva sets the "list price" for Nuvigil, confirming it is aware of the ultimate price paid for its brand drugs by consumers and payers.

304. But-for causation exists because if Teva, Pfizer, and Mylan had disclosed publicly everything they said in all their internal, secret communications, their scheme to defraud would not have succeeded because:

a. the federal courts would have invalidated their fraudulent settlement agreements;

b. the DOJ would have flagged and investigated their secret deal;

c. the FTC would have flagged and investigated their secret deal;

d. the FDA would have flagged and investigated their secret deal;

e. Congress would have asked Ms. Bresch and others about it at the 2016 hearing or held a hearing much earlier, had Teva, Mylan, and Pfizer not concealed their scheme to block generic competition; and/or

f. American payers and the media would have backlashed and stopped Teva, Mylan, and Pfizer in their tracks.

These forms of but-for causation are each independently sufficient on their own and are all questions of fact that require discovery to flesh out.

305. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs and Class members, and Plaintiffs and Class members are entitled to bring this action for three times their actual damages, as well as equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

E. Conspiracy Liability

306. Even if one of the Defendants is not responsible for violating RICO under 18 U.S.C. § 1962(c), they are still liable for conspiring to violate RICO under 1962(d).

307. Section 1962(d) reaches any conspiracy to violate the RICO statute, and each of the Defendants engaged in a conspiracy to violate the RICO statute by furthering the underlying scheme to defraud by Defendants, Mylan, and Pfizer.

308. Conspiracy liability under RICO is more broadly defined than traditional conspiracy law, and it permits the full civil penalties imposed by 18 U.S.C. § 1964(c).

DEMAND FOR JURY TRIAL

309. Plaintiffs respectfully demand a jury trial.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully request the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Classes;

B. Require Defendants to pay for sending notice to the certified Classes;

C. Appoint Plaintiffs as Class Representatives and Plaintiffs' counsel as Class Counsel;

D. Award equitable relief to correct for the anticompetitive market effects caused by Defendants' unlawful conduct and to ensure that similar anticompetitive conduct does not reoccur;

E. Award compensatory damages to Plaintiffs and the proposed Classes in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;

F. Award treble damages as permitted by law;

G. Award pre- and post-judgment interest at the highest rate allowed at law or equity;

H. Award punitive damages based on Defendants' reprehensible and deliberate conduct;

I. Award reasonable attorneys' fees and costs; and,

J. For all such other and further relief as may be just and proper.

DATED this 18th day of June, 2025.

KELLER ROHRBACK L.L.P.

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